

K060275 (p. 1 of 2)

9. SMDA Summary of Safety and Effectiveness – "510(k) Summary"A. Submitter Information

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SATELEC  
c/o Acteon, Inc.  
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Date Prepared: January 30, 2006

B. Device Identification

Common Usual Name: Ultrasonic scaler

Proprietary Name: Piezotome™

C. Identification of Predicate Device

<u>Device</u>	<u>Applicant</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
Suprasson® P5 Newtron	Satelec	K050895	April 20, 2005

The Satelec Piezotome™ is substantially equivalent to the predicate device by Satelec, the Suprasson® P5 Newtron (K050895) previously cleared by the FDA and currently marketed.

D. Device Description

The Piezotome™ is an ultrasonic scaler for use by dental practitioners.

The Piezotome™ device uses piezoelectric ultrasound technology to generate mechanical microvibrations for ultrasonic scaling, with minimal trauma to soft tissue.

In Newtron® function, it can be used for mechanical ultrasound treatment in prophylaxis, periodontics, endodontics or prosthesis.

This device is fitted with two handpiece cord connectors. Depending on the

application, the practitioner may connect two handpieces at the same time.

The Piezotome™ function offers four utilization modes at pre-set ultrasound power settings. In Newtron® function, the power of the ultrasound can be finely adjusted by the user.

Range	Ultrasound power	Procedure
Green	Low	Periodontics mainly
Yellow	Medium	Endodontics mainly
Blue	High	Prophylaxis mainly
Orange	Very high	Prosthesis or Specific treatment modalities

The user regulates the flow rate of the irrigation fluid.

The practitioner controls the device using a keyboard and a multi-function footswitch.

The irrigation fluid flow rate and the ultrasound power are monitored on a screen. For enhanced efficacy, the last settings are memorized by the machine.

#### E. Substantial Equivalence

The Piezotome™ and the predicate device, Suprasson® P5 Newtron (K050895) are both ultrasonic scalers for use in conventional dentistry by trained dental practitioners. Differences that exist between the devices relating to technical specifications, performances and intended use are minor and do not affect the safety and effectiveness of the Piezotome™.



MAY 3 2006

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

SATELEC  
C/O Mr. Steve Salesky  
Regulatory Affairs  
Acteon, Incorporated  
130 Gaither Drive, Suite 100  
Mount Laurel, New Jersey 08054

Re: K060275  
Trade/Device Name: Piezotome™  
Regulation Number: 872.4850  
Regulation Name: Ultrasonic Scaler  
Regulatory Class: II  
Product Code: ELC  
Dated: January 30, 2006  
Received: February 2, 2006

Dear Mr. Salesky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Chiu Lin', with a stylized flourish at the end.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number:

K060275

Device Name:

**Piezotome™**

Indications for Use:

**Periodontics  
Endodontics  
Scaling  
Prosthesis**

Please refer to the attached listing for a detailed description.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE  
IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Kevin Mulvey for MGP*  
(Signature)  
Department of Anesthesiology, General Hospital,  
Food and Drug Administration Control, Dental Devices  
Number K060275

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**INDICATIONS FOR USE**  
**Piezotome™**

**Periodontics:**

- Root planing
- Initial therapy
- Treatment of periodontal pockets
- Treatment of furcations
- Maintenance therapy
- Implant maintenance

**Endodontics:**

- Canal preparation
- Canal cleaning
- Canal filling
- Gutta percha condensation
- Treatment resumption
- Retro Surgery
- Micro Retro Surgery

**Scaling (prophylaxis):**

- Interdental junction treatment
- Tooth neck and subgingival treatment
- Treatment of large deposits
- Treatment of coating and tobacco stains
- Interproximal treatment

**Prosthesis (conservative/restorative):**

- Inlay/onlay condensation
- Amalgam plugging
- Loosening prostheses (bridge, crown, post, pivot...)



Chief of Endodontics, General Hospital,  
in Control, Dental Devices

Number K060275